REMARKS

Claims 1-17 are pending in the instant application. Claims 6 and 9-17 have been withdrawn from consideration by the Examiner and subsequently canceled, without prejudice, by Applicants. Claims 1-5 and 7-8 have been rejected. Claim 1 has been amended. Support for these amendments is provided in the specification at page 13, line 30, through page 14, line 5, page 14, line 14, through page 16, line 11, page 32, lines 15 through 19, and Examples 1 and 2 at pages 115-118. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Restriction Requirement mailed June 6, 2003 has been made final. Accordingly, Applicants have canceled non-elected claims 6 and 9-17, without prejudice. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Claims

Claim 1 has been objected to due to inclusion of non-elected subject matter. Thus, in an earnest effort to advance the prosecution of this case, Application have amended claim 1 to

delete non-elected subject matter. Withdrawal of this objection is therefore respectfully requested.

III. Objection to the Disclosure

The disclosure has been objected to for containing embedded hyperlinks and/or other forms of browser-executable codes. Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to inactivate all embedded hyperlinks by removing "http" and "www" and simply referring to the world wide web. No new matter is added by this amendment and entry is respectfully requested. Withdrawal of this objection is respectfully requested in light of these amendments.

IV. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner suggests that the phrase "at least 60% identity" causes the claims to be vague and indefinite because it is unclear what criteria are being used to determine

one nucleic acid sequence has at least 60% identity to another.

Applicants respectfully traverse this rejection.

As mandated by MPEP § 2173.02; definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The patent application at page 13, lines 1-20 defines the term "percent sequence identity" as well as methods for aligning sequences and calculating their percent sequence identity. Accordingly, what is meant by this phrase is clear when read in light of the teachings of the specification. Thus, further clarification in the claims is not required and withdrawal of this rejection is respectfully requested.

V. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claim 1-5, 7 and 8 have been rejected under 35 U.S.C. § 101 because the Examiner suggests that the claimed invention lacks patentable utility. Claims 1-5, 7 and 8 have also been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Specifically, the Examiner suggests that the claimed invention is not supported by a specific, substantial and credible utility, or in the alternative, a well-established utility.

Applicants respectfully traverse these rejections.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that no data indicating specificity of SEQ ID NO:65 is provided. Applicants respectfully direct the Examiner to Examples 1 and 2 at pages 115-118 of the instant specification wherein SEQ ID NO:65 was shown to be breast specific by mRNA subtraction analysis and to be differentially expressed in breast cancer samples versus normal adjacent tissue thus indicating its utility as a diagnostic marker for cancer.

Further, the case law is also quite clear; mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:65 as a breast specific gene which is differentially expressed in breast cancer, satisfies the utility requirement of 35 U.S.C. § 101 and 112, first paragraph.

Thus, since the instant specification provides a specific

and substantial utility for SEQ ID NO:65, the instant specification meets the utility requirements as set forth in 35 U.S.C. § 101 and §112.

Withdrawal of these rejections is therefore respectfully requested.

VI. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed had possession of the claimed invention. The Examiner has acknowledged the specification to disclose SEQ ID NO:65 corresponding to DNA encoding BNA. However, the Examiner suggests that the specification provides insufficient written description to support gene sequences and sequences that hybridize to the antisense sequence of SEQ ID NO:65.

Applicants respectfully traverse this rejection.

The written description requirement of 35 U.S.C. § 112, first paragraph, as set forth in MPEP § 2163.02 requires that the

specification set forth definitive structural features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Claim 1, now amended to be drawn to a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO:110, comprising a nucleic acid sequence of SEQ ID NO:65, selectively hybridizing under stringent hybridization conditions and stringent wash conditions to a nucleic acid molecule comprising SEQ ID NO:65 or a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:110, or a nucleic acid molecule having at least 95% sequence identity to a nucleic acid molecule comprising SEQ ID NO:65 or a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:110 clearly sets forth such definitive structural features.

Further, Applicants have amended claim 1 in accordance with teachings throughout the specification and in particular in Examples 1 and 2 at pages 115-118 of the instant specification wherein SEQ ID NO:65 was shown to be breast specific by mRNA subtraction analysis and to be differentially expressed in breast cancer to state that the nucleic acid molecule is a differentially expressed in breast cancer, thus providing a further functional characteristic as well by which one of skill

in the art can predictably identify the encompassed molecules.

MPEP 2163.02 also requires that the specification must show that applicant was in possession of the claimed invention. Possession of a nucleic acid molecule that encodes an amino acid sequence of SEQ ID NO: 110 and a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 65 as set forth in parts (a) and (b) of claim 1, respectively, is clearly evidenced by teachings in the Sequence Listing of the instant application and Examples 1 and 2 beginning at page 115-118 wherein expression of this nucleic acid molecule is demonstrated to be breast cancer specific. Part (c) of claim 1 has been amended and is now drawn to a nucleic acid molecule that hybridizes to SEQ ID NO:65 or encodes an amino acid sequence of SEQ ID NO:110 under stringent hybridization conditions and stringent wash conditions. Applicants' possession of this invention is clearly evidenced by teachings at pages 14, line 14 through page 16, line 27 and page 31, line 23 through page 32, line 4, wherein a detailed description regarding determining nucleic acid molecules which hybridize under stringent conditions is set forth. Part (d) of claim 1 has also been amended to be drawn to a nucleic acid molecule that has at least 95% sequence identity to SEQ ID NO:65 or a nucleic acid molecule encoding SEQ ID NO:110 in accordance

with teachings at page 32, lines 18 and 30. Nucleic acid molecules with at least 95% sequence identity are thus described at page 32 of the specification and detailed methodologies for determining percent sequence identity are taught at pages 13 through 14 thus evidencing Applicants' possession of this invention.

Accordingly, the instant claims and specification meet the written description requirements of 35 U.S.C. 112, first paragraph as set forth in MPEP 2163.02. Therefore, withdrawal of this rejection is respectfully requested in light of the amendments to the claims and the above remarks.

VII. Rejection of Claim 1 under 35 U.S.C. § 102(b)

Claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Sigma Catalog (1990). The Examiner suggests that the Sigma Catalog discloses a nucleic acid molecule which hybridizes with the sequence of SEQ ID NO:65 at positions 536 to 537.

It is respectfully pointed out, however, that the claims have been amended and are now drawn to a nucleic acid molecule that selectively hybridizes to a nucleic acid molecule of SEQ ID NO:65 or encoding an amino acid sequence of SEQ ID NO:110 under

stringent hybridization conditions and stringent wash conditions. Accordingly, the sequence taught in Sigma Catalog which is suggested by the Examiner to hybridize at positions 536 and 537 of SEQ ID NO:65 does not meet the limitations of the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

VIII. Rejection of Claim 1 under 35 U.S.C. § 102(a)

Claim 1 has been rejected under 35 U.S.C. § 102(a) as being anticipated by Nagase et al. The Examiner suggests that Nagase et al. discloses a human cDNA nucleic acid molecule which has at least 60% sequence identity to the nucleic acid sequence of SEQ ID NO:65.

At the outset, it is respectfully pointed out that the Nagase reference does not actually teach the human cDNA. Instead it refers to a GenBank sequence which can be modified. Further, the sequence alignments provided by the Examiner in support of this rejection are dated February 22, 2001, which is subsequent to the priority date of the instant application. Thus, the validity of Nagase et al. as a prior art reference is questionable.

Further, it is respectfully pointed out, however, that the claims have been amended and are now drawn to a nucleic acid molecule having at least 95% sequence identity to a nucleic acid molecule of SEQ ID NO:65 or encoding an amino acid sequence of SEQ ID NO:110. Since Nagase et al. does not teach a cDNA with at least 95% identity as claimed, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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